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EXAMINER	
MELLER, M	
ART UNIT	**PAPER NUMBER**
1808	2

18M1/1003

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DATE MAILED: 10/03/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-23 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 24-54 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-23 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Claims 1-23 are pending.

Claims 1-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are confusing since the resin which has a target protein/peptide bound to it is claimed as being uncharged and charged. However, both of these cannot exist at once. The resin must be one or the other. It would appear to have to be uncharged since the claim is requiring a resin protein/peptide complex. If charged the complex could not exist since the protein/peptide would be desorbed.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-23 are rejected under 35 U.S.C. § 103 as being unpatentable over Sasaki et al. '79 or Sasaki et al. '82 taken with Kasche et al., Teichberg and Jost et al.

The claims are drawn to a resin protein/peptide complex which comprises a resin and a target protein/peptide bound thereto wherein said resin comprises a solid support matrix and an ionizable ligand.

Sasaki et al. '79 teaches enzymes adsorbed on Amberlite CG-50 at a pH of 4 where carboxyl groups of the Amberlite are not dissociated. When not dissociated, the Amberlite is uncharged. The resin can be eluted by increasing the pH so that the carboxyl groups are dissociated. This would produce a charged Amberlite, see abstract.

Sasaki et al. '82 teaches enzymes adsorbed on Amberlite similar to Sasaki '79.

Kasche et al. teaches a rapid protein purification using phenylbutylamine-Eupergit which is a novel method for large-scale procedures. It teaches that the hydrophobically adsorbed proteins can be selectively desorbed by changing the pH of the eluent so that there is electrostatic repulsion between positive charges on the adsorbed proteins and positively charged secondary amines on the adsorbent.

Teichberg teaches affinity-repulsion chromatography and how in such a procedure one would want to change the pH, ionic strength, temperature and polarity of the eluting solvent.

Jost et al. teaches the mode of adsorption of proteins to aliphatic and aromatic amines coupled to cyanogen bromide-activate agarose. The reference reports that negatively charged proteins like ovalbumin and beta-lactoglobulin were bound to alkyl- or arylamino-agaroses. And that the absence of the positive charge on the matrix resulted in the abolishment of binding, see entire reference.

It would appear that in each of these references that when the protein is adsorbed, the resin is uncharged.

It would have been obvious from these references in combination that changing the pH so that the Amberlite of Sasaki et al. ('79 or '82) is charged, there would be repulsion between the Amberlite and enzyme so that the enzyme would become desorbed.

For these reasons, the rejection is made and a prima facie case of obviousness has been established.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is (703) 308-6037.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

The fax number for this examiner is (703) 308-0294.

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1808